



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-6778]

Fostering Medical Innovation: Case for Quality Voluntary Medical Device Manufacturing and Product Quality Pilot Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA or Agency or we) Center for Devices and Radiological Health (CDRH or Center) is announcing its Case for Quality Voluntary Medical Device Manufacturing and Product Quality Pilot Program (CfQ Pilot Program). The CfQ Pilot Program is voluntary and intends to evaluate product and manufacturing quality within the medical device ecosystem. The CfQ Pilot Program also intends to explore the effectiveness of a quality maturity appraisal, the use of objective metrics, optimization of resources, and impact on quality culture. The pilot program seeks to demonstrate better patient safety and outcomes, a lower regulatory burden on demonstrating quality assurance, and assure safety and effectiveness during product development and manufacturing.

DATES: The CfQ Pilot Program will run from January 2, 2018, to December 28, 2018. See the "Participation" section for instructions on how to submit a request to participate.

ADDRESSES: You may submit comments as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2017-N-6778 for "Case for Quality Voluntary Medical Device Manufacturing and Product Quality Program."

Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the

prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Francisco Vicenty, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3426, Silver Spring MD 20993, 301-796-5577, [Francisco.vicenty@fda.hhs.gov](mailto:Francisco.vicenty@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

As part of CDRH's 2016-2017 strategic priority to "Promote a Culture of Quality and Organizational Excellence" (Ref. 1), CDRH envisions a future state where the medical device ecosystem is inherently focused on device features and manufacturing practices that have the greatest impact on product quality and patient safety. Historically, FDA has evaluated manufacturers' compliance with regulations governing the design and production of devices. Compliance with the Quality System regulation, 21 CFR part 820, (Ref. 2) is a baseline requirement for medical device manufacturing firms. Focusing on elevating manufacturing quality practices gives greater emphasis to these practices, which should correlate to higher quality outcomes. This allows FDA to adjust how we recognize and incentivize behaviors and processes through which the safety and effectiveness of a medical device is assured. CDRH intends to continue working with stakeholders to assess and promote manufacturers' implementation of manufacturing quality practices in routine device design and production.

Through collaboration with the Medical Device Innovation Consortium (MDIC) over the last 2 years, a maturity model and appraisal system (i.e., Capability Maturity Model Integration (CMMI) system) that can be adapted for the medical device industry was selected (Ref. 3) for this CfQ Pilot Program. The CMMI system is a process level improvement, training, and appraisal

program. The CMMI Institute administers this program whose stated goal is to help organizations discover the true value they can deliver by building capability in their people and processes (Ref. 4). This model has been successfully used in various industries, including information technology, healthcare, automotive, defense, and aerospace to consistently deliver high quality products and reduce waste and defects. The CMMI Institute certifies and coordinates third party appraisers evaluating voluntary industry participants and any data necessary to demonstrate product performance. The appraiser would evaluate the firm's quality system maturity and manufacturing processes, identify any gaps, and recognize when a participating firm performs above a compliance baseline. The CMMI maturity appraisal process is not intended to serve as an FDA inspection nor is it intended to be a new regulatory requirement. Conducting independent-assessments using a maturity model is intended to be a driver of continuous process and product improvement and add business value to voluntary participants in the CfQ Pilot Program.

Assessments under the CMMI Institute are classified as Standard CMMI Appraisal Method for Process Improvement (SCAMPI) elements. A gap assessment (SCAMPI-C) will be a part of the CfQ Pilot Program. SCAMPI-C is a critical tool for developing an in-depth understanding of the medical device manufacturer's current state of process performance. SCAMPI-C is a short and flexible appraisal. It is used to assess the adequacy of planned approaches to process implementation and to provide a quick analysis between the organization's processes and CMMI practices. SCAMPI-C is intended to provide a rich dataset that reflects organizational performance and a comparison of the medical device manufacturer's performance against the CMMI model.

FDA is announcing and soliciting participation for the voluntary medical device manufacturers CfQ Pilot Program. We intend to limit this voluntary pilot program to a maximum

of nine participants. By participating in the third-party appraisal (SCAMPI-C), medical device manufacturers will receive an independent assessment of manufacturing and product quality intended to demonstrate sustained organizational excellence. By participating in the voluntary CfQ Pilot Program, FDA intends to forego conducting surveillance inspections. FDA will still conduct “For Cause” inspections where appropriate. The CMMI Institute will share the results of the SCAMPI-C appraisal with the manufacturer and develop a summary report to share with CDRH. Data collected through the appraisal and pilot will help inform FDA on how to modify its requirements around surveillance and preapproval inspections, as well as the content of premarket manufacturing submissions in order to better allocate resources and that could reduce the regulatory burden to appraised firms. The Center will continue an open dialog with the participants selected for the CfQ Pilot Program, medical device manufacturers and welcomes any feedback. For more information on the CfQ Pilot Program and how to enroll, please visit the website, <http://mdic.org/cfq/enroll/>.

#### *A. Participation*

FDA seeks participation in the CfQ Pilot Program beginning January 2, 2018. The CfQ Pilot Program will select up to nine participants who provide a holistic representation of the medical device industry and meet the selection criteria.

Companies that may be eligible to participate in this voluntary CfQ Pilot Program are limited to those firms following the procedures set out in section B and that also meet the selection qualities that follow:

1. The company must be in good compliance standing (No Action Indicated or Voluntary Action Indicated classification from FDA inspection or MDSAP (Medical Device Single Audit Program) audit within the last 5 years).

2. While participating in the CfQ Pilot Program, the company must agree to:

- a. Appraisal(s) conducted by the CMMI Institute.
- b. Collect and submit developed metric data and provide it to CMMI for analysis.  
Details and templates for the data are provided as part of the scoping discussions for the appraisal.
- c. Be available for real-time consultations with FDA and CMMI.
- d. Participate in established monitoring activities with CMMI.
- e. Allow for reporting to FDA by CMMI of analyzed performance data.

#### *B. Procedures*

To be considered for the CfQ Pilot Program, a company should enroll at <http://mdic.org/cfq/enroll/> or contact the CMMI Institute if you have questions at [medicaldevice@cmmiinstitute.com](mailto:medicaldevice@cmmiinstitute.com). Additional details of the proposed process for the CfQ Pilot Program can be found at the following website: <http://mdic.org/cfq/enroll/>.

During this CfQ Pilot Program, CDRH staff intends to be available to answer questions or concerns that may arise. The CfQ Pilot Program participants may comment on and discuss their experiences throughout the process with the Center and CMMI Institute.

#### II. Paperwork Reduction Act of 1995

This notice refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 820, regarding the Quality System regulations, have

been approved under OMB control number 0910-0073.

### III. References

The following references are on display in the Dockets Management Staff (see ADDRESSES), and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

1. CDRH, 2016-2017 "Promote a Culture of Quality and Organizational Excellence" available at:  
<https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHVisionandMission/UCM481588.pdf> and CDRH's Case for Quality Initiative available at:  
<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm378185.htm>.
2. The Quality System regulation available at: <https://www.ecfr.gov/cgi-bin/text-idx?SID=54a4a38f9c25eeab900b1c8f6c0f4212&mc=true&node=pt21.8.820&rgn=div5>.
3. MDIC available at: <http://mdic.org/>.
4. CMMI system available at: <http://cmmiinstitute.com/>.

Dated: December 22, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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